IN THE UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF MISSOURI

)	
CHRISTINA JUAREZ)	
PLAINTIFF,)	CASE NO.:
V.)))	COMPLAINT AND JURY DEMAND
BAYER CORPORATION;)	
BAYER HEALTHCARE LLC;)	
BAYER HEALTHCARE)	
PHARMACEUTICALS, INC.;)	
BAYER SCHERING PHARMA AG;)	
BAYER AG)	
)	
Defendants.)	

Plaintiff, by and through counsel, and for her Complaint against Defendants, alleges as follows:

PARTIES AND JURISDICTION

- 1. Plaintiff Christina Juarez is a resident and citizen of Kansas City, Missouri, located in Jackson County, Missouri.
- 2. Plaintiff Christina Juarez was prescribed and ingested Yasmin, and while using Yasmin she suffered a deep vein thrombosis and pulmonary embolism in March of 2007.
- 3. Plaintiff alleges an amount in controversy in excess of Seventy-Five Thousand Dollars (\$75,000.00), exclusive of interest and costs.
- 4. Defendant Bayer Corporation is an Indiana corporation with its principal place of business at 100 Bayer Road, Pittsburgh, Pennsylvania 15205. Defendant Bayer Corporation is engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, supplying, selling, marketing, and/or introducing into interstate commerce, either

directly or indirectly through third parties or related entities, its products, including the prescription drugs Yasmin and Yaz. At all relevant times, Defendant Bayer Corporation conducted regular and sustained business in Missouri by selling and distributing its products throughout the state of Missouri and throughout the United States.

- 5. Defendant Bayer Healthcare Pharmaceuticals, Inc. is a Delaware corporation, with its principal place of business at 6 West Belt Road, Wayne, New Jersey 07470. Bayer Healthcare Pharmaceuticals, Inc. was created by the integration of Bayer Healthcare and a company formerly known as Berlex Laboratories. Defendant Bayer Healthcare Pharmaceuticals, Inc. is engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, supplying, selling, marketing, and/or introducing into interstate commerce, either directly or indirectly through third parties or related entities, its products, including the prescription drugs Yasmin and Yaz. At all relevant times, Defendant Bayer Healthcare Pharmaceuticals, Inc. conducted regular and sustained business in Missouri by selling and distributing its products throughout the state of Missouri and throughout the United States.
- 6. Defendant Bayer Healthcare, LLC is a Delaware company, with its principal place of business at 555 White Plains Road, Tarrytown, New York 10591. Bayer Healthcare, LLC was involved in the integration of Bayer Healthcare and Berlex Laboratories. Defendant Bayer Healthcare, LLC is a citizen and resident of New York and is engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, supplying, selling, marketing, and/or introducing into interstate commerce, either directly or indirectly through third parties or related entities, its products, including the prescription drugs Yasmin and Yaz. At all relevant times, Defendant Bayer Healthcare, LLC conducted regular and sustained business in New York by selling and distributing its products throughout the state of Missouri and throughout the United States.

- 7. Defendant Bayer Schering Pharma AG is a foreign company headquartered in Berlin, Germany. Bayer Schering Pharma AG is the corporate successor to Schering AG, which was acquired by Bayer AG in 2006. As a result of the acquisition, Schering AG was renamed Bayer Schering Pharma AG. At all times relevant, Defendant Bayer Schering Pharma AG, and/or its corporate predecessors, has been engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, supplying, selling, marketing, and/or introducing into interstate commerce, either directly or indirectly through third parties or related entities, its products, including the prescription drugs Yasmin and Yaz. At all relevant times, Defendant Bayer Schering Pharma AG, and/or its corporate predecessors, conducted regular and sustained business in Missouri and by selling and distributing its products throughout the state of Missouri and throughout the United States.
- 8. Defendant Bayer AG is a foreign company headquartered in Leverkusen, Germany and is the parent company and/or holding company for several Bayer entities known collectively as the Bayer Group, which includes the Bayer Defendants named herein. At all relevant times, Defendant Bayer AG one or more of its groups or divisions has been engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, supplying, selling, marketing, and/or introducing into interstate commerce, either directly or indirectly through third parties or related entities, its products, including the prescription drugs Yasmin and Yaz. At all relevant times, Defendant Bayer AG conducted regular and sustained business in Missouri and by selling and distributing its products throughout the state of Missouri and throughout the United States.
- 9. Berlex Laboratories, Inc. was a Delaware corporation with its principal place of business in Montville, New Jersey. Berlex Laboratories, Inc. was integrated with Bayer Healthcare, leading to the creation of Bayer Healthcare Pharmaceuticals, Inc. Prior to being

Laboratories, Inc. was engaged in the business of researching, developing, designing, licensing, manufacturing, supplying, distributing, selling, marketing, and/or introducing into interstate commerce, either directly or indirectly through third parties or related entities, its products, including the prescription drugs Yasmin and Yaz. At all relevant times, Berlex Laboratories, Inc. conducted regular and sustained business in Missouri by selling and distributing its products throughout the state of Missouri and throughout the United States.

- 10. Defendants Bayer Corporation, Bayer Healthcare Pharmaceuticals, Inc., Bayer Healthcare, LLC, Bayer Schering Pharma AG, and Bayer AG are collectively referred to herein as "Bayer" or "Defendants."
- 11. This court has jurisdiction over this action pursuant to 28 U.S.C. §1332 because there is complete diversity of citizenship between the parties, and the amount in controversy exceeds \$75,000.00, exclusive of interest and costs.
- 12. This Court has personal jurisdiction over Defendants consistent with the United States Constitution as Plaintiff's claims arise out of Defendants' transaction of business and the commission of tortious acts within the State of Missouri, and by virtue of Defendants' substantial, continuous and systematic contacts with the State of Missouri unrelated to Plaintiff's claims.
- 13. Venue in this district is appropriate under 28 U.S.C. §1391(a) because a substantial part of the events giving rise to the claims asserted herein occurred in this District.

FACTUAL BACKGROUND

Nature of the Case

14. Plaintiff Christina Juarez brings this case against Defendants for damages associated with her ingestion of the pharmaceutical drug Yasmin (ethinyl estradiol and

drospirenone), which is an oral contraceptive designed, manufactured, supplied, marketed, and distributed by Defendants. Plaintiff Christina Juarez was diagnosed with a deep vein thrombosis and pulmonary embolism in March of 2007 as a direct result of her use of Yasmin.

<u>Bayer's Combined Oral Contraceptives – Yasmin and Yaz</u>

- 15. Yasmin and Yaz are birth control pills manufactured and marketed by Bayer. They are combination oral contraceptives, or "COCs," meaning that they contain an estrogen component and a progestin component. Together, these steroidal components work together in COCs to suppress ovulation, fertilization, and implantation and thus prevent pregnancy.
- 16. Yasmin and Yaz were approved by the Food and Drug Administration for marketing in 2001 and 2006 respectively.

Yasmin and Yaz Contain a "Fourth Generation" Progestin

- 17. The estrogen component in Yasmin and Yaz is known generically as ethinyl estradiol. The progestin component is known as drospirenone. Yasmin contains 0.03 milligrams of ethinyl estradiol, and Yaz contains 0.02 milligrams of ethinyl estradiol. Both products contain 3 milligrams of drospirenone.
- 18. Yasmin and Yaz are different from other combined hormonal birth control pills in that they contain drospirenone, a progestin that is unlike other progestins available in the United States and was never before marketed in the United States prior to its use in Yasmin.
- 19. Shortly after the introduction of combined oral contraceptives in the 1960's, doctors and researchers found that women using birth control pills had a higher risk of blood clots, heart attacks, and strokes than women not using the pill. As a result, the various brands of birth control pills were reformulated to reduce the amounts of estrogen. As the amounts of estrogen levels reduced, so too did the risk of blood clots, heart attacks, and strokes.

- 20. During this time, new progestins were being developed, which became known as "second generation" progestins (e.g. lovenorgestrel). These second generation progestins, when combined with the lower amounts of the estrogen, ethinyl estradiol, helped to reduce the risk of blood clots, heart attacks, and strokes and were considered safer for women.
- 21. During the 1990's, new "third generation" progestins were developed. Unfortunately, these "third generation" progestins (e.g. gestodene and desogestrel) have been associated with a greater risk of blood clots in the deep veins (deep vein thrombosis or "DVT") and lungs (pulmonary embolism or "PE"). As a result of this increased risk of blood clots, the FDA has required that products containing third generation progestins include a Warning of the potentially increased risk of thrombosis.
- 22. Yasmin and Yaz contain the same estrogen component, ethinyl estradiol, that has been used in the lower dose birth control pills for decades.
- 23. However, drospirenone is a new type of progestin and is considered a "fourth generation" progestin. No other birth control pills contain drospirenone, except for a recently approved generic version of Yasmin and Yaz marketed under the trade name Ocella.
- 24. Since drospirenone is new, there are not decades of data available to support its safe use as there are with second generation progestins. Studies that were done prior to FDA approval, however, indicate that drospirenone has certain effects that are different from those of traditional second generation progestins, and potentially more dangerous.
- 25. One possible mechanism of action is that drospirenone interacts differently with ethinyl estradiol compared to other progestins, such that it does not sufficiently counterbalance the clotting effects of estrogen as do other progestins, particularly the second generation progestins.

- 26. Another possible mechanism of action is that drospirenone causes an increase in potassium levels in the blood, which can lead to a condition known as hyperkalemia if the potassium levels become too high.
- 27. Hyperkalemia can cause heart rhythm disturbances, such as extrasystolies, pauses, or bradycardia. If left untreated, hyperkalemia can be fatal.
- 28. If hyperkalemia disrupts the normal heart rhythms, the flow of blood through the heart can be slowed to the point that it permits blood clots to form. Blood clots in the heart can then lead to heart attacks, or the clots can break off and travel to the lungs where they can cause pulmonary embolism, or can travel to the brain causing stroke.
- 29. Indeed, during the brief time that Yasmin and Yaz have been sold in the United States, hundreds of reports of injury and death have been submitted to the FDA in association with Defendants' products.
- 30. In April 2002, the British Medical Journal reported that the Dutch College of General Practitioners recommended that older second generation birth control pills be prescribed in lieu of Yasmin as a result of 40 cases of venous thrombosis among women taking Yasmin.
- 31. In February 2003, a paper entitled *Thromboembolism Associated With the New Contraceptive Yasmin* was published in the British Medical Journal detailing a Netherlands Pharmacovigilance Centre report of five additional reports of thromboembolism where Yasmin was suspected as the cause, including two deaths.
- 32. More recently, in May of 2009, two separate studies were published in the British Medical Journal concluding that there is an increased risk of venous thrombotic events associated with combined oral contraceptives containing drospirenone.
- 33. One paper published in the British Medical Journal on May 27, 2009 entitled, Hormonal contraception and risk of venous thromboembolis: national follow-up study,

concluded that oral contraceptives containing drospirenone were associated with a significantly higher risk of venous thrombosis than oral contraceptives containing levonorgestrel, a second generation progestin.

- 34. The other paper published in the British Medical Journal on May 29, 2009 entitled, *The venous thrombotic risk of oral contraceptives, effects of oestrogen dose and progestogen type: results of the MEGA case-control study*, concluded that there was a 6.3 fold increased risk of venous thrombotic events associated with oral contraceptives containing drospirenone.
- 35. In fact, in less than a five-year period, from the first quarter of 2004 through the third quarter of 2008, over 50 reports of death among users of Yasmin and Yaz have been filed with the FDA.
- 36. These reports include deaths associated with cardiac arrhythmia, cardiac arrest, intracardiac thrombus, pulmonary embolism, and stroke in women in their child bearing years.
 - 37. Some deaths reported occurred in women as young as 17 years old.
- 38. Significantly, reports of elevated potassium levels are frequently included among the symptoms of those suffering death while using Yasmin or Yaz.

Over-Promotion of Yasmin and Yaz

- 39. Defendants market Yasmin and Yaz as providing the same efficacy as other birth control pills in preventing pregnancy, but with additional benefits.
- 40. However, because Yasmin and Yaz contain the fourth generation progestin drospirenone, they present additional health risks not associated with other birth control pills.
- 41. For example, prior to its integration with Defendant Bayer in 2006, Berlex Laboratories promoted Yasmin's fourth generation progestin, drospirenone, by stating, "Ask about Yasmin, and the difference a little chemistry can make."

- 42. In response, on July 10, 2003, the FDA objected to the characterization that drospirenone was a benefit compared to the progestin used in other combined oral contraceptives and issued a warning letter stating, "FDA is not aware of substantial evidence of substantial clinical experience demonstrating that Yasmin is superior to other COCs or that the drospirenone in Yasmin is clinically beneficial. On the contrary, FDA is aware of the added clinical risks associated with drospirenone [.]"
- 43. The FDA's warning letter continued by stating that the advertisement failed "to communicate that the potential to increase potassium is a risk" or that "increased serum potassium can be dangerous."
- 44. More recently, Defendants advertised that its product Yaz was indicated for treatment of premenstrual syndrome or "PMS," as opposed to the less serious condition of premenstrual dysphoric disorder or "PMDD."
- 45. Defendants also advertised that Yaz contained the added benefit of preventing or reducing acne.
- 46. In response, on October 3, 2008, the FDA issued another warning letter to Defendant Bayer for the misleading advertisement, reiterating that the marketing was misleading because it promoted Yaz for medical conditions beyond the limits of the FDA approval, and adding that "Yaz has additional risks because it contains the progestin, drospirenone ... which can lead to hyperkalemia in high risk patients, which may result in potentially serious heart and health problems."
- 47. The FDA further warned in its October 3, 2008 letter that Yaz "does not result in completely clear skin" and that Defendants' "TV Ads misleadingly overstate the efficacy of the drug."

- 48. Indeed, the FDA felt Defendants' overpromotion of Yasmin was so severe that it required Bayer to run new TV advertisements to correct the previous misleading Yaz advertisements regarding acne and premenstrual syndrome.
- 49. Bayer ultimately agreed to spend at least \$20 million on corrective TV advertisements and to submit all Yaz advertisements to the FDA for advanced screening for the next six years.
- 50. Most recently, on August 5, 2009, the FDA issued another warning letter to Defendant Bayer regarding the FDA's March 2009 inspection of Bayer's active pharmaceutical ingredient facility in Bergkamen, Germany. In its letter, the FDA warned that based on its inspection, Bayer's "quality management system fails to ensure that API's [active pharmaceutical ingredients] manufactured and released by [Bayer] meet established specifications." The active pharmaceutical ingredient drospirenone was specifically referred to by the FDA as one of the ingredients identified as manufactured and released out of specification.
- 51. Thus, not only is there evidence based on published scientific literature that Yasmin and Yaz inherently present an increased risk of venous thrombotic events when compared to other oral contraceptives, but there is also evidence of potential manufacturing irregularities associated with Yasmin and Yaz.

Plaintiff's Use of Yasmin and Resulting Injuries

52. As a result of Defendants' claim regarding the effectiveness and safety of Yasmin, Plaintiff Christina Juarez's medical provider prescribed and Christina Juarez began using Yasmin in or about March of 2006. Plaintiff Christina Juarez used Yasmin through March, 2007, at which time she suffered a deep vein thrombosis and pulmonary embolism.

- 53. Plaintiff Christina Juarez was hospitalized for approximately seven days as a result of her use of Yasmin and resulting deep vein thrombosis and pulmonary embolism.
- 54. As a direct and proximate result of using Yasmin, Plaintiff Christina Juarez suffered the injuries described above.
- 55. Prior to Plaintiff's use of Yasmin, Defendants knew or should have known that use of Yasmin created a higher risk of deep vein thrombosis and pulmonary embolism than other oral contraceptives on the market, including but not limited to second generation oral contraceptives, and that, when taken as directed, such use was unreasonably dangerous to consumers.
- 56. Therefore, at the time Plaintiff used Yasmin, Defendants knew or should have known that the use of Yasmin created an increased risk to consumers of serious personal injury, including deep vein thrombosis, pulmonary embolism, heart attacks, stroke, and even death.
- 57. Despite the fact that Defendants knew or should have known of the serious health risks associated with the use of Yasmin, Defendants failed to adequately warn Plaintiff Christina Juarez and/or her health care providers of said serious risks before she used the products.
- 58. Had Plaintiff Christina Juarez and/or her heath care providers known of the increased risks and dangers associated with Yasmin, she would not have used the product and would not have suffered a deep vein thrombosis and pulmonary embolism in March of 2007.
- 59. As a direct and proximate result of her use of Yasmin, Plaintiff Christina Juarez has suffered significant harm, conscious pain and suffering, physical injury and bodily impairment, which may have caused permanent effects, and which may continue in the future to cause her physical effects and damage which will affect her throughout her lifetime.
- 60. Further, as a direct and proximate result of her use of Yasmin, Plaintiff Christina Juarez has suffered significant mental anguish and emotional distress and will continue to suffer

physical limitations, pain, injury, damages, harm, and mental and emotional distress in the future.

61. Plaintiff Christina Juarez has also incurred medical expenses and other economic harm and will continue to incur such expenses in the future, as a direct and proximate result of her use of Yasmin.

FIRST CAUSE OF ACTION

Strict Products Liability Defective Manufacturing

- 62. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows.
- 63. Defendants are the manufacturers, designers, distributors, sellers, and/or suppliers of Yasmin.
- 64. The Yasmin oral contraceptive manufactured, designed, sold, distributed, supplied and/or placed in the stream of commerce by Defendants was defective in its manufacture and construction such that it was unreasonably dangerous, was not fit for the ordinary purpose for which it was intended, and/or did not meet the reasonable expectations of an ordinary consumer.
- 65. The Yasmin oral contraceptive manufactured, designed, sold, distributed, supplied and/or placed in the stream of commerce by Defendants, was defective in its manufacture and construction as described at the time it left the Defendants' control.
- 66. As a direct and proximate result of Plaintiff's use of Yasmin as manufactured, designed, sold, supplied and introduced into the stream of commerce by Defendants, Plaintiff Christina Juarez suffered personal injury, economic and non-economic damages, and will continue to suffer such harm, damages, and economic loss in the future.

67. Defendants' conduct as alleged in this Complaint demonstrates that Defendants acted maliciously, wantonly, or with recklessness suggesting an improper motive so as to warrant the imposition of punitive damages.

SECOND CAUSE OF ACTION

Strict Products Liability Defect in Design or Formulation

- 68. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows.
- 69. Defendants are the manufacturers, designers, distributors, sellers, or suppliers of Yasmin.
- 70. The Yasmin oral contraceptive manufactured, designed, sold, distributed, supplied and/or placed in the stream of commerce by Defendants was defective in its design such that it was unreasonably dangerous, was not fit for the ordinary purpose for which it was intended, and/or did not meet the reasonable expectations or an ordinary consumer.
- 71. At the time Defendants manufactured, designed, distributed, sold, and/or supplied the Yasmin oral contraceptive into the stream of commerce, a safer, more practical, alternative design was available.
- 72. The Yasmin oral contraceptive manufactured, designed, sold, distributed, supplied, and/or placed in the stream of commerce by Defendants, was defective in design as described above at the time it left the Defendants' control.
- 73. As a direct and proximate result of Plaintiff's use of Yasmin as manufactured, designed, sold, supplied and introduced into the stream of commerce by Defendants, Plaintiff Christina Juarez suffered personal injury, economic and non-economic damages, and will continue to suffer such harm, damages, and economic loss in the future.

74. Defendants' conduct as alleged in this Complaint demonstrates that Defendants acted maliciously, wantonly, or with recklessness suggesting an improper motive so as to warrant the imposition of punitive damages.

THIRD CAUSE OF ACTION

Strict Products Liability Defect Due to Inadequate Warning

- 75. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows.
- 76. Defendants are the manufacturers, designers, distributors, sellers, or suppliers of Yasmin.
- 77. The Yasmin oral contraceptive manufactured and supplied by Defendants was defective due to inadequate warning or instruction, because Defendants knew or should have known that the product was unreasonably dangerous in that it created a substantial increased risk of serious bodily harm and death to reasonably foreseeable consumers such as Plaintiff Christina Juarez, and Defendants failed to adequately warn consumers and/or their health care providers of such increased risk.
- 78. The Yasmin oral contraceptive manufactured and supplied by Defendants was also defective due to inadequate post-marketing warning or instruction, because, after Defendants knew or should have known of the risk of serious bodily harm and death from the use of Yasmin, Defendants failed to provide adequate warning to consumers and/or their health care providers of the product, knowing the product could cause serious injury and death.
- 79. As a direct and proximate result of Plaintiff's use of Yasmin as manufactured, designed, sold, supplied and introduced into the stream of commerce by Defendants, Plaintiff

Christina Juarez suffered personal injury, economic and non-economic damages, and will continue to suffer such harm, damages, and economic loss in the future.

80. Defendants' conduct as alleged in this Complaint demonstrates that Defendants acted maliciously, wantonly, or with recklessness suggesting an improper motive so as to warrant the imposition of punitive damages.

FOURTH CAUSE OF ACTION

Strict Products Liability Defect Due to Nonconformance with Representations

- 81. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows.
- 82. Defendants are the manufacturers, designers, distributors, sellers, or suppliers of Yasmin, and they made representations regarding the character or quality of Yasmin.
- 83. The Yasmin oral contraceptive manufactured and supplied by Defendants was defective in that, when it left the hands of Defendants, it did not conform to representations made by Defendants concerning the product.
- 84. Plaintiff Christina Juarez justifiably relied upon Defendants' representations regarding the Yasmin oral contraceptive when she used Yasmin.
- 85. As a direct and proximate result of Plaintiff's use of Yasmin and her reliance on Defendants' representations regarding the character and quality of Yasmin, Plaintiff Christina Juarez suffered personal injury, economic and non-economic damages, and will continue to suffer such harm, damages, and economic loss in the future.
- 86. Defendants' conduct as alleged in this Complaint demonstrates that Defendants acted maliciously, wantonly, or with recklessness suggesting an improper motive so as to warrant the imposition of punitive damages.

FIFTH CAUSE OF ACTION

Strict Products Liability Defect Due to Failure to Adequately Test

- 87. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows.
- 88. Defendants advised consumers and the medical community that Yasmin contained the same safety profile as other oral hormonal birth control pills. However, Defendants failed to adequately test the safety of Yasmin versus other oral hormonal birth control pills.
- 89. Had Defendants adequately tested the safety of Yasmin versus other oral hormonal birth control pills and disclosed the results to the medical community or the public, Plaintiff would not have used, and her physician would not have prescribed, Yasmin.
- 90. As a direct and proximate result of Defendants' failure to adequately test the safety of Yasmin versus other oral hormonal birth control pills, Plaintiff Christina Juarez suffered personal injury, economic and non-economic damages, and will continue to suffer such harm, damages, and economic loss in the future.
- 91. Defendants' conduct as alleged in this Complaint demonstrates that Defendants acted maliciously, wantonly, or with recklessness suggesting an improper motive so as to warrant the imposition of punitive damages.

SIXTH CAUSE OF ACTION

Negligence

92. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows.

- 93. Defendants had a duty to exercise reasonable care in the manufacture, design, sale, distribution, supply, marketing, and/or placement of Yasmin into the stream of commerce, including a duty to ensure that its product did not pose a significantly increased risk of bodily harm and adverse events.
- 94. Defendants failed to exercise ordinary care in the design, formulation, manufacture, sale, testing, quality assurance, quality control, labeling, marketing, promotions and distribution of Yasmin into interstate commerce in that Defendants knew, or should have known, that the product caused such significant bodily harm or death and was not safe for use by consumers.
- 95. Defendants also failed to exercise ordinary care in the labeling of Yasmin and failed to issue to consumers and/or their health care providers adequate warnings of the increased risk of serious bodily injury or death due to the use of Yasmin.
- 96. Despite the fact that Defendants knew or should have known that Yasmin posed a serious increased risk of bodily harm to consumers, Defendants continued to manufacture and market Yasmin for use by consumers.
- 97. Defendants knew or should have known that consumers, such as Plaintiff Christina Juarez, would foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care as described above.
- 98. As a direct and proximate result of Defendants' negligence, Plaintiff Christina Juarez suffered personal injury, economic and non-economic damages, and will continue to suffer such harm, damages, and economic loss in the future.
- 99. Defendants' conduct as alleged in this Complaint demonstrates that Defendants acted maliciously, wantonly, or with recklessness suggesting an improper motive so as to warrant the imposition of punitive damages.

SEVENTH CAUSE OF ACTION

Breach of Express Warranty

- 100. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows.
- 101. Defendants expressly warranted that Yasmin was a safe and effective prescription oral contraceptive.
- 102. The Yasmin birth control product manufactured and sold by Defendants did not conform to these express representations because it caused serious injury to consumers who used the product when taken in the recommended dosages.
- 103. As a direct and proximate result of Defendants' breach of warranty, Plaintiff Christina Juarez suffered personal injury, economic and non-economic damages, and will continue to suffer such harm, damages, and economic loss in the future.
- 104. Defendants' conduct as alleged in this Complaint demonstrates that Defendants acted maliciously, wantonly, or with recklessness suggesting an improper motive so as to warrant the imposition of punitive damages.

EIGHTH CAUSE OF ACTION

Breach of Implied Warranty

- 105. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows.
- 106. At the time Defendants manufactured, marketed, sold, and distributed Yasmin, Defendants knew of the use for which Yasmin was intended and impliedly warranted Yasmin to be of merchantable quality, fitness, and safe for such use.

- 107. Plaintiff Christina Juarez and her health care provider reasonably relied upon the skill and judgment of Defendants as to whether Yasmin was of merchantable quality and safe for its intended use and upon Defendants' implied warranty as to such matters.
- 108. Contrary to the implied warranty, Defendants' product Yasmin was not of merchantable quality or safe for its intended use, because it was unreasonably dangerous as described herein.
- 109. As a direct and proximate result of Defendants' breach of warranty, Plaintiff Christina Juarez suffered personal injury, economic and non-economic damages, and will continue to suffer such harm, damages, and economic loss in the future.
- 110. Defendants' conduct as alleged in this Complaint demonstrates that Defendants acted maliciously, wantonly, or with recklessness suggesting an improper motive so as to warrant the imposition of punitive damages.

NINTH CAUSE OF ACTION

Negligent Misrepresentation and/or Fraud

- 111. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows:
- 112. Defendants are the manufacturers, designers, distributors, sellers or suppliers of Yasmin and, while engaged in the course of such business, made representations to Plaintiff and her physician regarding the character and/or quality of Yasmin for guidance in their decision to select Yasmin for Plaintiff's use.
- 113. Specifically, Defendants represented that their product was just as safe, and just as effective or more effective, than other birth control products on the market.
- 114. Defendants' representations regarding the character or quality of Yasmin were untrue.

- 115. Defendants had actual knowledge based upon studies, published reports and clinical experience that its product Yasmin created an unreasonable increased risk of serious bodily injury and death to consumers, or should have known such information.
- 116. Defendants negligently and/or intentionally misrepresented or omitted this information in its product labeling, promotions and advertisements and instead labeled, promoted and advertised its product as safe and effective in order to avoid losses and sustain profits in its sales to consumers.
- 117. In supplying the false information, Defendants failed to exercise reasonable care or competence in obtaining or communicating information to their intended recipients, including Plaintiff and her physician.
- 118. Plaintiff Christina Juarez and her physician reasonably relied to her detriment upon Defendants' misrepresentations and/or omissions in its labeling, advertisements, and promotions concerning the serious risks posed by the product. Plaintiff Christina Juarez reasonably relied upon Defendants' representations to her and/or her health care providers that Yasmin was just as safe and effective as other types of oral contraceptives for human consumption and/or use and that Defendants' labeling, advertisements and promotions fully described all known risks of the product.
- 119. As a direct and proximate result of Defendants' negligent and/or intentional misrepresentations, Plaintiff Christina Juarez suffered personal injury, economic and non-economic damages, and will continue to suffer such harm, damages, and economic loss in the future.
- 120. Defendants' conduct as alleged in this Complaint demonstrates that Defendants acted maliciously, wantonly, or with recklessness suggesting an improper motive so as to warrant the imposition of punitive damages.

TENTH CAUSE OF ACTION

Violation of Missouri Merchandising Practices Act

- 121. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows.
- 122. Defendants knew, or in the exercise of reasonable care should have known, that Yasmin was not reasonably safe as designed, manufactured, tested, marketed and distributed.
- 123. Defendants knew that Yasmin carried the increased risk of serious adverse events, including thrombotic injuries such as blood clots, pulmonary emboli, and strokes.
- 124. Defendants' actions, representations, and/or omissions constitute unlawful commercial practices in connection with the sale of merchandise and false advertising and were deceptive and misleading practices within the meaning of Missouri's Merchandising Practices Act, Mo. Rev. Stat. §§ 407.010 to 407.307.
- 125. By reason of the foregoing, Plaintiff was and will be caused bodily injury, pain, suffering, and economic loss.
- 126. By reason of the foregoing, Plaintiff is entitled to damages and attorneys' fees and permitted by the Missouri Merchandising Practices Act.

WHEREFORE, Plaintiff prays for relief as follows:

- 1. Compensatory damages in excess of the jurisdictional amount, including, but not limited to pain, suffering, emotional distress, loss of enjoyment of life, and other non-economic damages in an amount to be determined at trial of this action;
- 2. Medical expenses and other economic damages in an amount to be determined at trial of this action;
 - 3. Punitive and exemplary damages;
 - 4. Attorneys' fees, expenses, and costs of this action; and

5. Such further relief as this Court deems necessary, just, and proper.

JURY DEMAND

Plaintiff hereby demands a trial by jury on all issues so triable.

Dated: December 11, 2009 Respectfully submitted,

/s/__Lee J. Hollis_

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